

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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GEORG NEBGEN, PARVIZ GHAHRAMANI and
THERAHOLDINGS AG (SA Ltd.),

Civil Action No.
18-cv-8410

Plaintiffs,

- against -

JEROME J. SCHENTAG, MARY P. McCOURT,
LAWRENCE MIELNICKI, JULIE HUGHES and
THERASYN SENSORS, INC.,

Defendants.

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COMPLAINT

Georg Nebgen ("Nebgen"), Parviz Ghahramani ("Ghahramani") and TheraHoldings AG (SA, Ltd.) ("TheraHoldings") (collectively "Plaintiffs"), by their attorneys, Schlam Stone & Dolan LLP and Law Offices of Philip A. Kantor, P.C., for their complaint against Jerome J. Schentag ("Schentag"), Mary P. McCourt ("McCourt"), Lawrence Mielnicki ("Mielnicki"), Julie Hughes ("Hughes") and TheraSyn Sensors, Inc. ("TheraSyn") (collectively "Defendants"), respectfully allege as follows:

The Parties

1. TheraHoldings is a corporation formed under the laws of Switzerland with its principal place of business at Giessenstrasse 41, 8835 Feusisberg, Switzerland.

2. Nebgen is an individual residing at Giessenstrasse 41, 8835 Feusisberg, Switzerland.

3. Ghahramani is an individual residing in New Jersey.

4. Schentag is an individual, upon information and belief, residing at 100 Crosby Boulevard, Eggertsville, New York 14226-3246.

5. McCourt is an individual, upon information and belief, residing at 15 Colonial Road, Amherst, New York 14226.

6. Mielnicki is an individual, upon information and belief, residing at 725 Ashland Avenue, Buffalo, New York 14222.

7. Hughes is an individual, upon information and belief, residing at 16 Char Del Way, Williamsville, New York 14221.

8. TheraSyn, upon information and belief, is a Delaware corporation with its principal place of business c/o of Jerome J. Schentag, 100 Crosby Boulevard, Eggertsville, New York 14226-3246.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, in that (i) Plaintiff Georg Nebgen resides in Switzerland and is a citizen of Germany;

Plaintiff Parviz Ghahramani resides in New Jersey and is a citizen of the United States; Plaintiff TheraHoldings is a corporation formed under the laws of Switzerland and maintains its principal place of business in Switzerland; (ii) Defendants Jerome Schentag, Mary McCourt, Lawrence Mielnicki and Julie Hughes are, upon information and belief, residents of New York and citizens of the United States; Defendant TheraSyn is a corporation formed under the laws of Delaware and maintains its principal place of business in New York; and (iii) the amount in controversy, exclusive of interest and costs, exceeds \$75,000.

10. This Court also has subject matter jurisdiction pursuant to 28 U.S.C §§ 1331 and 1338, and 35 U.S.C § 256, because the claims alleged herein, in part, arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and seek relief with respect to correcting the inventorship of one or more patents arising under the laws of the United States relating to patents.

11. Personal jurisdiction over the Defendants is proper, because all of the individual Defendants reside in the State of New York, and the corporate Defendant has its principal place of business in the State of New York.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391, in that a substantial part of the events or

omissions giving rise to plaintiffs' claims occurred in this District.

The Facts

13. This action concerns Defendants' attempt to misappropriate Plaintiffs' interest in a certain technology referred to herein as "cholestosome technology."

14. Cholestosome technology was invented by McCourt as early as 2006. Cholestosome technology provides for specialized vesicles, called "cholestosome vesicles," that carry a payload of any of a wide variety of therapeutics, including proteins, peptides, genes, and other molecules. A cholestosome vesicle is a nanoparticle formed of cholesteryl esters with a hollow compartment for receiving the payload. The payload-laden cholestosome vesicle is absorbed into the enterocyte membrane of the small intestine, and is then incorporated into a chylomicron to be transported, using the body's own lymphatic lipid delivery system, via the bloodstream into the cells of the body, where the cholestosome vesicle is ingested by the individual cells, and the encapsulated payload is released. Cholestosome technology allows injectable proteins and peptides, such as insulin, to be delivered orally.

15. On March 20, 2006, McCourt filed a U.S. provisional patent application, No. 60/784,118, entitled "Drug Delivery

Means," to cover aspects of cholestosome technology. On March 20, 2007, McCourt filed a non-provisional patent application, No. 11/725,831, claiming priority to the '118 provisional patent application. The '831 application matured into an issued patent, No. 9,119,782, on September 1, 2015. On June 17, 2015, McCourt filed a continuation patent application, No. 14/741,915 that has received a notice of allowance.

16. On March 14, 2013, McCourt, Mielnicki and Schentag filed a U.S. provisional patent application, No. 61/783,003, entitled "Cholestosome Vesicles for Incorporation Of Molecules Into Chylomicrons," to cover aspects of cholestosome technology. On March 14, 2014, McCourt, Mielnicki, Schentag and Hughes filed a Patent Cooperation Treaty ("PCT") application, No. PCT/US14/27761, claiming priority to the '003 application. On September 14, 2015, McCourt, Mielnicki, Schentag and Hughes filed a U.S. national stage application, No. 14/776,308. The '308 application matured into an issued patent, No. 9,693,968, on July 4, 2017. On May 24, 2017, McCourt, Mielnicki, Schentag and Hughes filed a continuation patent application, No. 15/603,992, that remains pending.

17. McCourt, Mielnicki, Schentag and Hughes filed a series of foreign patent applications based on PCT/US14/27761, namely, JP2016513712 in Japan; CN105164143 in China; EP2970369

in the European Union; AU2014236559 in Australia; BR112015022936 in Brazil; CA2905108 in Canada; HK1212354 in Hong Kong; IL241501D in Israel; and MX/a/2015/011462 in Mexico. Upon information and belief, all of these foreign patent applications are pending and in good standing.

18. On May 24, 2017, McCourt, Mielnicki, Schentag and Hughes filed a U.S. patent application, No. 15/63,992, that is a continuation of the '308 application, which also claims priority to the '003 provisional patent application. Upon information and belief, the '992 application remains pending and in good standing.

19. On August 23, 2016, McCourt, Mielnicki, Schentag and Hughes filed a U.S. provisional patent application, No. 62/378,599, entitled "Cholesteryl Ester Vesicles Loading Peptides, Proteins and Nucleic Acids into Chylomicrons and Body Cells," to cover aspects of cholestosome technology. On August 23, 2017, McCourt, Mielnicki, Schentag and Hughes filed a Patent Cooperation Treaty ("PCT") application, No. PCT/US2017/048135, claiming priority to the '599 application. The 30-month deadline, by which time the earliest national stage patent applications will need to be filed under PCT/US2017/048135, is February 23, 2019.

20. Upon information and belief, McCourt and Mielnicki are science research professionals and faculty members in the Department of Chemistry at Niagara University in Niagara, New York. Upon information and belief, Schentag is an Emeritus Professor of Pharmaceutical Sciences and Pharmacy at the University at Buffalo School of Pharmacy. Upon information and belief, Hughes is a research technologist at Niagara University.

21. Upon information and belief, prior to 2013, Schentag became acquainted with McCourt and Mielnicki, and became interested in their work on cholestosome technology. Taking this interest to the next step, Schentag persuaded McCourt and Mielnicki he had the experience and wherewithal to develop the cholestosome technology into marketplace products that would bring wealth and prestige to McCourt and Mielnicki.

22. Upon information and belief, Schentag insinuated himself into McCourt's and Mielnicki's work on cholestosome technology to where they agreed to name Schentag as an inventor on their patent applications for it, even though Schentag in fact contributed nothing to the inventions that would qualify him as an inventor within the meaning of 35 U.S.C. § 100.

23. Upon information and belief, Hughes was named as an inventor on McCourt's and Mielnicki's patent applications for cholestosome technology. However, Hughes in fact contributed

nothing to the inventions that would qualify her as an inventor within the meaning of 35 U.S.C. § 100.

24. In or around 2013, Schentag met Nebgen, and asked Nebgen to join with him, McCourt and Mielnicki in the development and commercial exploitation of cholestosome technology. Nebgen agreed to do so.

25. In furtherance of that agreement, Schentag, McCourt, Mielnicki and Nebgen decided to use Nebgen's wholly owned entity, TheraHoldings AG ("TheraHoldings"), a Swiss corporation with a nominal capital of 150,000 Swiss francs, to hold the patents and other intellectual property embodying the cholestosome technology, and to make Schentag, McCourt and Mielnicki shareholders of the corporation in return for contributing the IP and a \$15,000 down payment. In furtherance of the agreement, Nebgen sold 75% of his shares in TheraHoldings to Schentag, McCourt and Mielnicki.

26. On November 15, 2013, Schentag, Nebgen, McCourt and Mielnicki entered into a series of written agreements to carry out their joint venture. Schentag participated in the resulting structure through a personal holding corporation, namely,

TheraSyn, and Nebgen participated through a personal holding corporation, STEP UP Holding AG ("STEP UP").¹

27. The two main agreements signed by the parties to carry out their venture were the "Share Purchase Agreement" and the "Contribution Agreement." Under the Share Purchase Agreement, STEP UP, which owned 100% of the shares of TheraHoldings (totaling 300 shares), sold 120 shares to TheraSyn for Schentag; 53 shares to McCourt; and 52 shares to Mielnicki. In exchange for these shares, TheraSyn for Schentag, McCourt and Mielnicki each agreed to pay some cash money, and to contribute their interests on an ongoing basis in the patents embodying the cholestosome technology.²

28. The Contribution Agreement detailed Defendants' obligation to contribute the patent assets embodying the cholestosome technology to TheraHoldings as follows:

1. Contribution in kind

Subject to the terms and conditions agreed between the parties hereto, Contributors hereby will contribute their developed Intellectual Property Rights to

¹ In subsequent transactions, Schentag assumed ownership of his TheraHoldings shares from TheraSyn, and Nebgen assumed ownership of his TheraHoldings shares from STEP UP.

² They also agreed to contribute a third category of patent assets not related to cholestosome technology. However, it was later recognized that this third category of assets was not theirs to contribute, so it was later reversed out of the deal, and is irrelevant to this action.

the Company on a recurring basis. Initial contributions made to the Company are:

1) Drug Delivery Means
(US2007/0225264A);

2) Cholestosome Vesicles for
Incorporation of Molecules into
Chylomicrons, US Provisional 61/783,003
patent filed March 14, 2013); ...

29. The reference to "Drug Delivery Means
(US2007/0225264A)" above is to the patent family originating
with McCourt's first provisional patent application, namely, the
'118 patent application referred to in Paragraph 15 above. The
number used by the parties in the Contribution Agreement
("US2007/0225264A") was the patent publication number, which was
the most recent reference number available at the time of the
Contribution Agreement.

30. The reference to "Cholestosome Vesicles for
Incorporation of Molecules into Chylomicrons, US Provisional
61/783,003 patent filed March 14, 2013" is to the patent family
originating with the first provisional patent application filed
by the group of McCourt, Mielnicki, Schentag and Hughes, namely
the '003 patent application referred to in Paragraph 16 above.

31. Throughout the years following the signing of the
Contribution Agreement, Defendants repeatedly acknowledged
TheraHoldings' ownership of the patent families relating to
cholestosome technology. For example, as early as June 9, 2015,

in an email from Schentag to Henry Coleman (the parties' patent counsel) and McCourt, Schentag wrote that McCourt had freed up any encumbrance to the '831 patent application through an agreement with her employer, Niagara University, and that "Assignment by TheraHoldings A.G. is agreed upon by all parties." As late as March 22, 2017, Defendants supported a PowerPoint presentation to Bayer AG stating that "Cholestosome™ is a novel technology covered by several patents wholly owned by TheraHoldings."

32. On September 30, 2015, each of McCourt, Mielnicki and Schentag sold some of their TheraHoldings shares to Parviz Ghahramani, making Ghahramani a 5% owner of TheraHoldings. Ghahramani did not obligate himself to take any action on behalf of TheraHoldings when he purchased and paid for an interest in the cholestosome technology by acquiring shares in TheraHoldings.

33. In entering into these transactions with Ghahramani, Schentag, McCourt and Mielnicki each represented and warranted to Ghahramani, *inter alia*, that TheraHoldings was properly formed, each of them was the owner of the shares in TheraHoldings that they respectively were selling to Ghahramani, and that TheraHoldings was the owner of the cholestosome technology that was its principal asset.

34. Sometime between 2015 and 2017, however, Schentag hatched a scheme to steal Plaintiffs' interest in the cholestosome technology, and upon information and belief, recruited McCourt and Mielnicki to join him in that scheme. The essence of his scheme was to concoct some basis to renege on the obligations created by the Contribution Agreement, the Share Purchase Agreement, and Defendants' separate agreements with Parviz Ghahramani; to demand rescission of all of those agreements; and to misappropriate the cholestosome technology for Defendants' benefit despite the prior assignment of that technology to TheraHoldings.

35. In furtherance of that scheme, on October 3, 2017, Schentag wrote an email on behalf of McCourt, Mielnicki and himself, to Nebgen demanding the rescission of the 2013 TheraHoldings agreements, including the Contribution Agreement. Here is the text of the email in full:

TheraSyn Sensors, Inc

October 3, 2017

VIA E-MAIL

Dr. Georg Nebgen
Step Up Holding AG
Giessenstrasse 41
8835 Feusisberg
Switzerland

Re: Share Purchase Agreement dated November 15, 2013
between Step Up Holding AG, TheraSyn Sensors Inc.,
Mary P. McCourt and Lawrence Mielnicki

Dear Georg:

I have received numerous emails and other communications from you making baseless demands and alleging purported rights of TheraHoldings AG and Step Up Holdings AG pursuant to the above Purchase Agreement and certain related agreements referred to therein including, among others, a Contribution Agreement.

We entered into the above agreement based on your representations to both myself and Drs. McCourt and Mielnicki that you were experienced in obtaining venture capital and that you had extensive contacts. You further represented that if we entered into these agreements that you would not only raise capital to develop the patents but that you would be able to license or sell the underlying technology and intellectual property represented by these patents.

An integral part of your promises and representations was that you would finance the development and pay for the U.S. and foreign legal patent expenses. You insisted we enter into the purchase agreement before you would approach or reveal your contacts. Quite frankly, you have done nothing for four years and it is quite apparent there was no basis for the representations you made, and that you made them with knowledge of their falsity.

We made it quite clear several years ago that the patents would not be transferred to TheraHoldings AG since you, TheraHoldings and Step Up Holdings were in material breach of your respective obligations under our agreements. Since these

100 Crosby Blvd, Buffalo, NY 14226

TheraSyn Sensors, Inc

patents belonged to us, we paid for all subsequent research and legal expenses. We continued, at our expense, to develop the technologies, file new patents and retain patent counsel to develop the patents and intellectual property we own. You did not participate in any of this. In fact, you repeatedly rejected any suggestions that you had any obligations to participate in funding the activities respecting our patents or intellectual property.

TheraHoldings has no rights to these patents and intellectual property. Any claims TheraHoldings may have had to the portion of the intellectual property which existed in November 2013 was waived and discharged by your material breach several years ago. In addition, your misrepresentations have caused myself, TheraSyn Sensors Inc., and Drs. McCourt and Mielnicki substantial damages for which we intend to hold you responsible.

I demand that the Share Purchase Agreement and all related documents be rescinded, including, without limitation, the Contribution Agreement, the Loan Agreement and the Memorandum of Understanding, each dated November 15, 2013.

Very truly yours,



Dr. Jerome Schentag

cc: Mary P. McCourt, PhD.
Lawrence Mielnicki, PhD
Stephen M. Rosenberg, Esq.
Henry Coleman, Esq.

100 Crosby Blvd, Buffalo, NY 14226

36. The purported rescission of the 2013 TheraHoldings agreements was without justification, legally or factually.

37. The opening premise of the October 3 letter was that Nebgen represented that if McCourt, Mielnicki, Schentag and TheraSyn (the "Rescinding Defendants") entered the agreements, Nebgen would raise capital to develop the patents, and would be able to license or sell the underlying technology. However, no such representation – by way of recital or undertaking – exists in the 2013 agreements.

38. On the contrary, the Contribution Agreement provides that "TheraHoldings AG acquires the Intellectual Property Rights without recourse." (§ 3.) The Share Purchase Agreement provides that "[t]he Seller provides no further representations regarding shares of this Share Purchase Agreement other than those explicitly listed in this section 4." (§ 4.6.) It further provides that "[c]laims in case of breach of warranties and assurances according to section 4 can be made effective until June 30, 2014." (§ 6.1.) In regard to rescission, the Share Purchase Agreement provides that "[a] withdrawal from this agreement is excluded in any case and any legal title (including basic misapprehension or error)." (§ 7.1.).

39. The Contribution Agreement and the Share Purchase Agreement provide that they are governed by Swiss law. Under

Swiss law, the provisions quoted in paragraph 29 are enforceable according to their terms.

40. The October 3 letter further claimed that Nebgen (1) represented he would finance expenses for the patents, (2) refused to reveal his fundraising contacts until the Rescinding Defendants signed the agreements, and (3) did “nothing” for four years. Putting aside the fact that under Swiss law rescission could not be legally justified on any of these bases, the claims of the October 3 letter have no factual validity.

41. For example, on October 27, 2013, Nebgen wrote the following email to Schentag regarding the due diligence list of Stern Aegis, a venture capital firm Nebgen solicited to fund the cholestosome technology. The email *predates* the 2013 TheraHoldings agreements, and was unquestionably a reason the Rescinding Defendants were eager to enter those agreements:

From: Georg Nebgen
Sent: Sunday, October 27, 2013 1:18 PM
To: schentag@cplassociates.com <mailto:schentag@cplassociates.com>
Subject: Let's connect

Hi Jerry,

Let's have a phone call tomorrow to through the documents with your initial questions set timelines for the answer of the Due diligence list of Stern Aegis. We have to return it this week and I am traveling Thursday (my evening through) Sunday to Paris for an anniversary celebration with my spouse!

Would 9 am EST be a good time for you tomorrow?

42. Nebgen and Schentag worked assiduously with Stern Aegis on this multimillion dollar funding deal throughout 2013 and 2014, to the point of finalizing a term sheet. However, Schentag ultimately decided to reject the deal, hammering the final nail in the coffin during a team conference call on May 27 and a subsequent face-to-face meeting in Boston on June 9, 2014.

43. As for licensing or selling the underlying technology, Nebgen, with the help of Ghahramani, generated a great number of opportunities, contrary to the claim of the October 3 letter that Nebgen did "nothing." These opportunities have not yet borne fruit only because of the failures by the Rescinding Defendants to provide scientific data and other deliverables required by the counterparties to those deals. The following reflects the general nature of these opportunities.

44. The main purpose of cholestosome technology is to orally deliver therapeutic agents, or other chemicals or biologics, that would alternatively need to be delivered a different way, such as intravenously. Accordingly, Nebgen and Ghahramani, on behalf of TheraHoldings, contacted pharmaceutical companies making and selling these products, such as insulin, in order to persuade them to participate in tests using cholestosome vesicles to deliver the companies' proprietary products. The goal was to produce favorable enough results for the delivery and absorption of each particular pharmaceutical company's products to persuade the company to go further with funded research resulting in a long-term license. Each pharmaceutical company closely supervised and participated in the tests of its proprietary products, theoretically enabling the company to know firsthand whether cholestosome technology held promise for its products. The advantage of this approach to licensing – which the Rescinding Defendants strongly advocated – was that TheraHoldings could pursue many opportunities at the same time, since the tests involved different products of different companies, with the result that multiple non-conflicting licenses could be signed.

45. For example, Nebgen brought the well-known pharmaceutical company, Eli Lilly, into a test of two Lilly molecules. Lilly funded this test with a grant of \$129,135

pursuant to a "Technology Evaluation Agreement" signed on January 29, 2016, to be paid in phases. Pursuant to that grant, Lilly paid TheraHoldings \$86,000 for the first two phases, from which TheraHoldings, in turn, paid \$77,000 to laboratories under the management of the Rescinding Defendants for the production of cholestosome vesicles and other work on the test. However, the Rescinding Defendants – who exclusively ran the laboratory operations of TheraHoldings – were unable to produce the vancomycin cholestosome formulation required for the Lilly test, as shown in the following email responding to Lilly's declaration that it "need[ed] to pull the plug on this work tomorrow if the material won't be here in time" (see, bottom of email string):

JS Jerome Schentag <schentag@cplassociates.com> Kurt Van Scoik; amrrtober@aol.com; Jerome Schentag; Georg Nebgen; + 1 = 8/18/2016
 RE: upcoming Vancomycin study

Hi Kurt

At this point, we do not think we will have what Phenil needs on the 23rd.

It is our agreement that the Vancomycin cholestosome formulation needs to be provided in at least 20mg/ml solution in order to dose each rat with 0.5-1.0ml of product

Our problem is making a stable solution of vancomycin that is concentrated down into 20mg in 1.0ml. Vancomycin preps start out around 2.0 mg/ml, and although we have been thru a number of the usual concentrating processes, vancomycin is refusing to cooperate. It is not stable at that concentration.

Today we are doing a round of lyophilization tests, but even if these succeed we are still a ways away from having the necessary amount of product for testing on August 23rd.

So at the very least, we are causing a delay and we apologize for that.

If this is worse, we will also know that by mid next week, and we propose a discussion conference call next Friday when we have all the results and when everybody is back in Buffalo.

Please let us know if that would work, and thanks for your patience.

Jerome J Schentag, PharmD
 Chief Scientific Officer
 TheraHoldings AG
 Giessenstrasse 41
 8835 Feusisberg
 Switzerland
 US Phone 1-716-867-0550
 US Fax: 1-716-633-3331
schentag@buffalo.edu

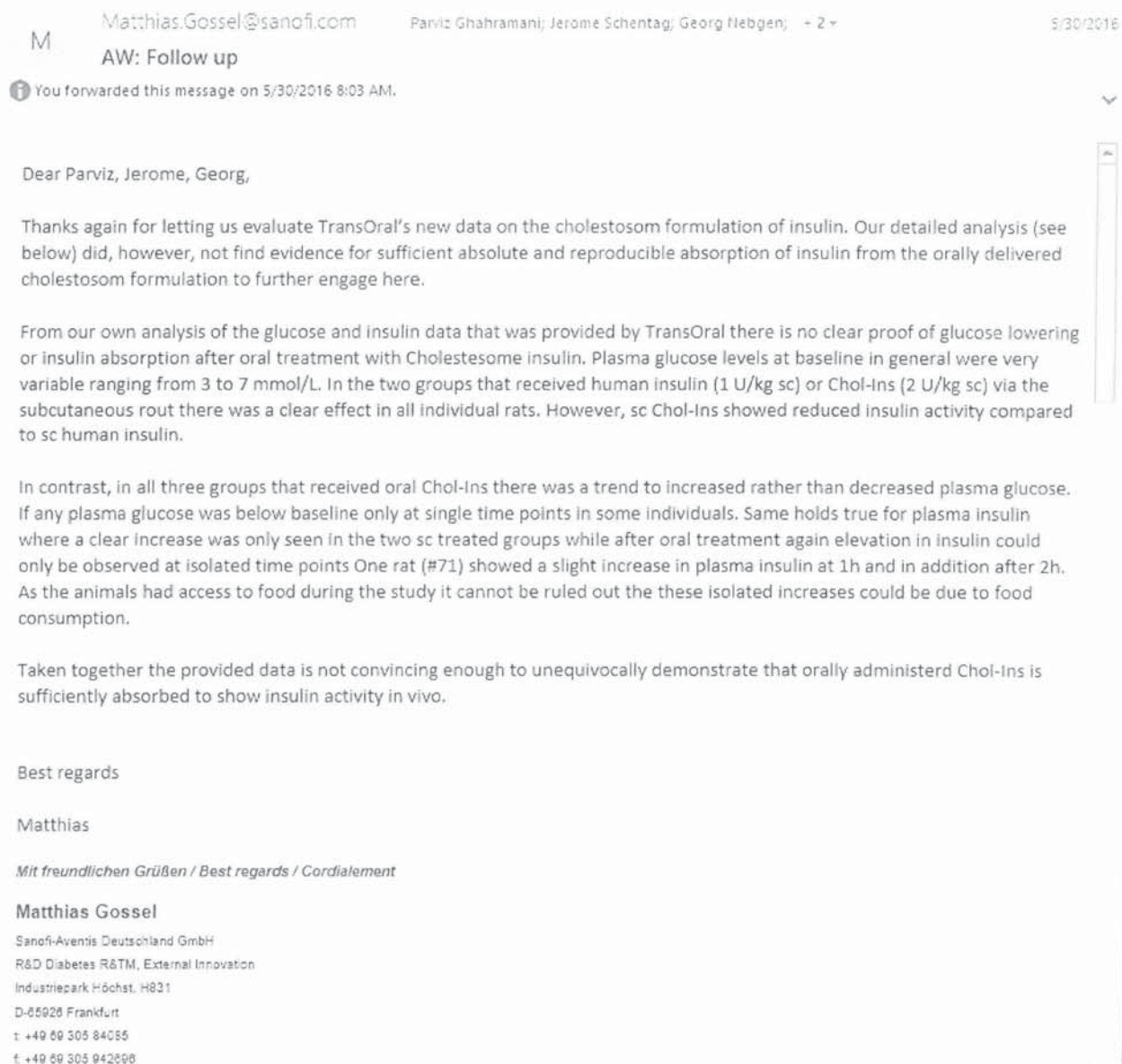
From: Kurt Van Scoik [mailto:van_scoik_kurt@lilly.com]
 Sent: Thursday, August 18, 2016 1:09 PM
 To: amrrtober@aol.com; Jerome Schentag <JSchentag@cplassociates.com>
 Cc: Georg Nebgen (gnebgen@VIVANT-HOLDINGS.COM) <gnebgen@VIVANT-HOLDINGS.COM>; Phenil J. Patel <patel_phenil_j@lilly.com>
 Subject: upcoming Vancomycin study

Hi Mary and Jerry...can you please provide us with an update on sending the encapsulated vancomycin to Phenil? We need to pull the plug on this work tomorrow if the material won't be here in time.

46. Similarly, on behalf of TheraHoldings, Nebgen negotiated with the well-known pharmaceutical company, Bristol Myers Squibb, for a test of cholestosome technology with selected proprietary products. Bristol Myers Squibb funded this test with a sign-on payment of \$70,000 plus up to \$70,000 upon completion of various milestones, pursuant to a "Feasibility Study Agreement" effective December 7, 2015. The funds were

paid to TheraHoldings, from which TheraHoldings, in turn, paid \$50,000 to laboratories under the management of the Rescinding Defendants for the production of cholestosome vesicles and other work on the test. However, the Rescinding Defendants – who exclusively ran the laboratory operations of TheraHoldings – were unable to reach the required milestones. The Rescinding Defendants refused, *inter alia*, to produce the scientific report for BMS and to confirm destruction of materials as requested by BMS, or to share any data with Plaintiffs.

47. Similarly, Nebgen brought the well-known pharmaceutical company, Sanofi, to TheraHoldings for a test of cholestosome technology with long-acting insulin products pursuant to a “Material Transfer Agreement” signed on June 23, 2015. However, the Rescinding Defendants – who exclusively ran the laboratory operations of TheraHoldings – were unable to produce the evidence of sufficient absolute and reproducible absorption required by Sanofi:



48. Though this initially marked the end of the Sanofi test, Ghahramani – not the Rescinding Defendants – saved the test as shown in the following two emails:

Von: Parviz Ghahramani [mailto:PGhahramani@volantpharma.com]
Gesendet: Freitag, 17. Juni 2016 16:42
An: Gossel, Matthias R&D/DE; Werner, Ulrich R&D/DE; Urmann, Matthias R&D/DE
Cc: Jerome Schentag; Georg Nebgen
Betreff: RE: Follow up

Dear Matthias,

Thanks for the reply and for reviewing the data. We talked in details about your response internally at Volant, and quite frankly we are surprised about some of the statements in the response, especially about the oral absorption of insulin. We noticed that in part of your email (highlighted below) it appears you have assumed the assay measures endogenous rat insulin as well as administered human insulin. We see that this assumption may have lead you to conclude the concentrations of Insulin measured in the study are influenced by food consumption. We would like to draw your attention to a few critical facts to provide you with accurate information as follows:

1. The assay we used (Mercodia kit) does not pick up (or cross-react) with rat endogenous insulin and, therefore, food consumption would not have any effect on the insulin concentrations measured in this study (obviously because we administered human insulin and the assay does not pick up rat insulin).
2. As part of this rat study we assayed blank rat plasma samples using the Mercodia kit. Our results confirm that the assay does not pick up any concentration of rat insulin. This finding is consistent with the product information (as advertised) by the manufacturer of the kit, where they clearly state this assay does not cross-react with rat insulin.
3. We agree there is variability in the baseline insulin concentrations observed in 1-2 animals in the study. But, the human Insulin concentrations (in particular the AUCs) after the oral Cholestosome insulin and regular sc Insulin are comparable. The fact that we have considerable measured Insulin levels in this study after oral Cholestosome insulin (at levels that are far above limit of quantification of the assay), is a strong evidence of oral absorption by Cholestosome technology. The extent of absorption needs to be of course examined in further studies especially now that we have a better idea what doses are suitable to use in rats and knowing that we have to improve on the assay variability in the next studies forthcoming.

We hope the information above address some of the points you stated in your email.

Kind regards

Parviz

Von: Gossel, Matthias R&D/DE
Gesendet: Freitag, 1. Juli 2016 17:43
An: 'Parviz Ghahramani'
Cc: Jerome Schentag; Georg Nebgen; Werner, Ulrich R&D/DE; Urmann, Matthias R&D/DE; Lerche, Christian R&D/DE; Wendt, Ulrich R&D/DE
Betreff: AW: Follow up

Dear Parviz,

Sorry for the late response, I was travelling during the last two weeks.

Your comments are well taken and brought us to reconsider our assessment.

While insulin data indeed suggest an interesting effect, the accompanying data on glucose are much too variable to allow an overall assessment.

We therefore suggest to re-enter again into a feasibility study under the recently renewed MTA, with an adapted study plan aiming to provide a less variable and more consistent overall picture.

If this is acceptable to you, we are looking forward to start working with you on a consolidated a study plan

Best regards

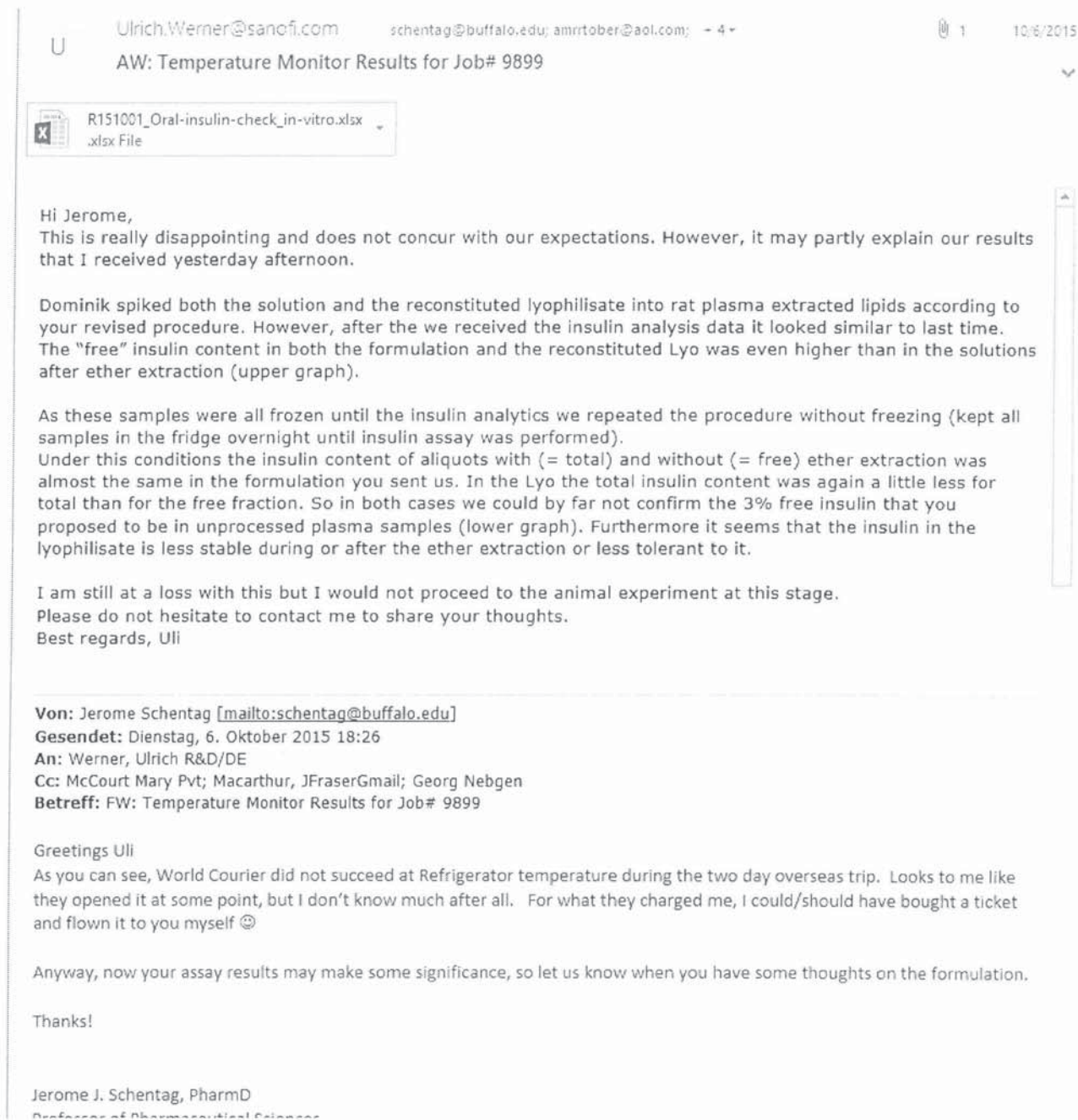
Matthias

Mit freundlichen Grüßen / Best regards / Cordialement

Matthias Gossel

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f: +49 69 305 942696
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49. Despite Plaintiffs' efforts to save this test, Sanofi lost patience and terminated the test based on the non-reproducibility of data and stability problems, both issues that were under the exclusive purview of the Rescinding Defendants. Indeed, Sanofi expressed frustration on multiple occasions with the Rescinding Defendants' inability even to ship materials to Germany, for example:



50. Further, the Rescinding Defendants concealed laboratory progress from Plaintiffs Nebgen and Ghahramani.

51. In addition to the foregoing, on behalf of TheraHoldings, Nebgen made presentations to the following

companies, among others: Roche Holding AG, AstraZeneca, OrbiMed and Asling.

52. The Rescinding Defendants' claim in the October 3 letter – that Nebgen promised and represented he would pay for U.S. and foreign legal patent expenses – is false, among other things, because title to these properties was assigned by the 2013 TheraHoldings agreements to TheraHoldings, not Nebgen. Nothing in those Agreements, or otherwise, gave rise to any obligation by Nebgen to pay these expenses, and he never obligated himself personally to do so. Further, Schentag controlled the management of patent counsel (Henry Coleman) on behalf of TheraHoldings, and improperly withheld access to the management of patent counsel from Nebgen, including billing.

53. In furtherance of Defendants' scheme as aforesaid, upon information and belief, on or around May 1, 2018, McCourt executed an assignment agreement purporting to assign the '831 patent application to TheraSyn (the "2018 Purported Assignment"). The 2018 Purported Assignment was dated "effective October 4, 2013," despite the fact that the '831 patent application had already been assigned by her to TheraHoldings on November 15, 2013 pursuant to the 2013 TheraHoldings agreements.

54. In furtherance of Defendants' scheme as aforesaid, upon information and belief, on or around May 1, 2018, Schentag and/or TheraSyn caused the 2018 Purported Assignment to be recorded in the United States Patent & Trademark Office.

55. The foregoing facts are inconsistent with the claims of the October 3 letter. Far from justifying rescission of the 2013 TheraHoldings agreements, these facts show that Plaintiffs acted loyally and diligently to further the goals of developing the cholestosome technology, and to license or sell it. These facts also show that TheraHoldings' lack of success to date was caused by the Rescinding Defendants' failure to provide acceptable scientific data and other deliverables required by the counterparties to the development deals procured by Plaintiffs, rather than any act or omission by Plaintiffs.

56. Indeed, these facts show that the Rescinding Defendants hatched the scheme, as aforesaid, to steal Plaintiffs' interest in and legal rights to the cholestosome technology, to misappropriate Plaintiffs' substantial investments and contributions to TheraHoldings, in order to keep the cholestosome technology for themselves. Upon information and belief, the Rescinding Defendants are actively seeking, or may have already identified and pursued, opportunities to develop the cholestosome technology, and to license or sell it,

that have been kept secret from Plaintiffs, and are not being shared with Plaintiffs. Wherefore, Plaintiffs pray that the Court intercede to prevent the Rescinding Defendants from rescinding the 2013 TheraHoldings agreements, and from pursuing separate opportunities to develop, license or sell the cholestosome technology.

CLAIM I

DECLARATORY JUDGMENT UPHOLDING THE
2013 TERAHOLDINGS AGREEMENTS

57. Plaintiffs repeat and reallege the allegations of Paragraphs 1 through 56 as though set forth in full here.

58. The Rescinding Defendants duly entered into the 2013 TheraHoldings agreements, including, but not limited to the Share Purchase Agreement dated November 15, 2013, and the Contribution Agreement dated November 15, 2013. These agreements provide that they are governed by the laws of Switzerland.

59. The terms of the 2013 TheraHoldings agreements do not permit rescission, and those provisions are fully enforceable under Swiss law. Further, there are no facts justifying rescission. Rather, the facts support the validity of the 2013 TheraHoldings agreements.

60. A dispute has arisen between Plaintiffs and Defendants Schentag, McCourt and Mielnicki as to the validity of TheraHoldings' ownership of the rights assigned to it in the cholestosome technology.

61. Plaintiffs have no adequate remedy at law, and absent a declaratory judgment of this Court, will be damaged by Defendants' conduct as aforesaid.

62. Plaintiffs respectfully request that the Court issue a declaratory judgment finding and determining that (i) the 2013 TheraHoldings agreements are valid and in force, (ii) are not rescinded, and (iii) as between Defendants and Plaintiffs, TheraHoldings is the rightful owner of the cholestosome technology previously assigned to it. Plaintiffs further request an injunction, directing Defendants to take all necessary steps to cooperate with the process of applying for patent and other intellectual property protection of the cholestosome technology around the world, as well as with the process of maintaining and expanding such protection, in the name of TheraHoldings.

COUNT II

DECLARATORY JUDGMENT AS TO PLAINTIFFS GHARAMANI AND NEBGEN

63. Plaintiffs repeat and reallege the allegations of Paragraphs 1 through 62, as though set forth in full here.

64. In September 2015, Defendants Schentag, McCourt and Mielnicki sold, and Ghahramani bought from them and paid for, shares in TheraHoldings. In September 2015, Defendant Schentag also sold seven (7) shares in TheraHoldings to Nebgen for 3500 Swiss francs.

65. Defendants Schentag, McCourt and Mielnicki now seek to rescind the agreements with TheraHoldings whereby TheraHoldings obtained rights in and to the cholestosome technology as its principal asset.

66. There is no basis in law or equity under which Defendants Schentag, McCourt and Mielnicki can rescind those agreements, thus depriving Plaintiffs Ghahramani and Nebgen of the benefit of their bargain with them.

67. A dispute has arisen between Plaintiffs Ghahramani and Nebgen and Defendants Schentag, McCourt and Mielnicki as to the validity of TheraHoldings' ownership of the rights assigned to it in the cholestosome technology.

68. Plaintiffs Ghahramani and Nebgen have no adequate remedy at law, and absent a declaratory judgment of this Court, will be damaged by Defendants' conduct as aforesaid.

69. Plaintiffs Ghahramani and Nebgen respectfully request that the Court issue a declaratory judgment that (i) the

2013 TheraHoldings agreements are valid and in force, (ii) are not rescinded, and (iii) as between Defendants and Plaintiffs, TheraHoldings is the rightful owner of the cholestosome technology previously assigned to it. Plaintiff further requests an injunction, directing Defendants to take all necessary steps to cooperate with the process of applying for patent and other intellectual property protection of the cholestosome technology around the world, as well as with the process of maintaining and expanding such protection, in the name of TheraHoldings.

COUNT III

BREACH OF FIDUCIARY DUTY

70. Plaintiffs repeat and reallege the allegations of Paragraphs 1 through 69 as though set forth in full here.

71. Schentag, McCourt, Mielnicki and Plaintiffs formed a joint venture for the purpose of developing and exploiting the cholestosome technology. In connection with that joint venture, Schentag, McCourt, Mielnicki and Plaintiffs formed TheraHoldings, and Schentag became Chief Scientific Officer of TheraHoldings and acted as such at all applicable times.

72. By reason of the foregoing, Schentag owed a fiduciary duty as an officer and shareholder to TheraHoldings, and to TheraHoldings' other officers, directors and

shareholders, to act in the best interests of the corporation. Notwithstanding his fiduciary duty, Schentag acted against the best interests of TheraHoldings by claiming, without justification, that the cholestosome technology, and all related patents and patent applications around the world, do not belong to TheraHoldings.

73. Upon information and belief, Schentag acted against the best interests of TheraHoldings by inducing McCourt and Mielnicki to similarly claim, without justification, that the cholestosome technology, and all related patents and patent applications around the world, do not belong to TheraHoldings.

74. Upon information and belief, Schentag acted against the best interests of TheraHoldings by inducing McCourt to purport to assign the '831 patent application family to TheraSyn, and to record this purported assignment with the United States Patent & Trademark Office, despite the fact that these properties were assigned, and belong to TheraHoldings.

75. As a result of these and other actions by Schentag, a cloud has been cast upon TheraHoldings' ownership of cholestosome technology, preventing TheraHoldings from carrying on its business operations. Among other things, because of Defendants' wrongful acts as aforesaid, TheraHoldings cannot now engage in such business operations as fundraising activity,

licensing and sale activity, research and development activity, and patent prosecution activity.

76. Schentag's breach of fiduciary duty has also caused reputational harm to TheraHoldings.

77. Schentag is accordingly liable to Plaintiffs for the damages his breach of fiduciary duty has caused them in an amount to be determined at trial, but not less than \$10,000,000.

78. As a result of the foregoing, Schentag is required to account to Plaintiffs for all opportunities and revenues diverted from TheraHoldings as a result of Schentag's breach of fiduciary duty.

COUNT IV

CORRECTION OF NAMED INVENTORS

79. Plaintiffs repeat and reallege the allegations of Paragraphs 1 through 78 as though set forth in full here.

80. Upon information and belief, Schentag and Hughes contributed nothing to any of the inventions comprising the cholestosome technology that would qualify them as inventors within the meaning of 35 U.S.C. § 100. Notwithstanding, both Schentag and Hughes are named inventors on several of the patents and patent applications referenced in this complaint as embodying the cholestosome technology, and possibly on other

patents and patent applications not referenced in this complaint. Pursuant to 35 U.S.C. § 256, Schentag and Hughes should rightfully be removed as named inventors on these patents and, separately, Schentag and Hughes should rightfully be removed as named inventors on patent applications for the cholestosome technology not yet issued as patents.

81. Accordingly, Plaintiffs respectfully request an order authorizing them, and directing Defendants, to take such actions, including but not limited to an appropriate submission to the Patent Office under 35 U.S.C. § 116, to remove Schentag and Hughes as co-inventors of American patents for the cholestosome technology. Further, Plaintiffs respectfully request an order authorizing them, and directing Defendants, to take such actions, as necessary, to remove Schentag and Hughes as co-inventors of non-American patents, as well as pending patent applications in the United States and worldwide, for the cholestosome technology.

WHEREFORE, Plaintiffs demand that judgment be entered in their favor and against Defendants as follows: (a) declaring that the 2013 TheraHoldings agreements are valid and in force, and are not rescinded; (b) enjoining Defendants to take all necessary steps to cooperate with the process of applying for patent and other intellectual property protection of the

cholesterol technology around the world, as well as with the process of maintaining and expanding such protection, in the name of TheraHoldings; (c) awarding damages against Schentag for his breach of fiduciary duty in an amount to be determined at trial, but not less than \$10,000,000; (d) granting an accounting by Schentag of opportunities and revenues diverted from TheraHoldings as a result of his breach of fiduciary duty; (e) authorizing Plaintiffs, and directing Defendants, to take such actions, including but not limited to an appropriate submission to the Patent Office under 35 U.S.C. § 116, to remove Schentag and Hughes as co-inventors of American patents for the cholesterol technology, and to take such actions, as necessary, to remove Schentag and Hughes as co-inventors of non-American patents, as well as pending patent applications in the United States and worldwide, for the cholesterol technology; (f) awarding Plaintiffs pre-judgment interest at the statutory rate on the value of all benefits Schentag has obtained by his breach of fiduciary duty; and (g) granting Plaintiffs such other

and further relief, including the costs and disbursements of this action, as to the Court seems just and proper.

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New York, New York

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